RYDER SCIENCE
.....medical biofilm research

To: HIPAC
From: Marcia Ryder PhD MS RN
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Re: Draft guidelines for the Prevention of Intravascular Catheter-Related Infections

Dear distinguished committee members,

Thank you for the opportunity to comment of the 2009 Draft document. Your work on this challenging assignment is appreciated especially in view of the daunting amount of literature to be reviewed and considered on this topic and the serious nature of the work.
In the interest of time, the comments will be brief and to the point. Given this, please know that the intent is to be helpful and constructive from a scientific and evidence-based point of view.

1. **Recommendations for peripheral catheters and midline catheters**
   page 13; line 292.
   5. Use a midline catheter or peripherally inserted central catheter (PICC), instead of a short peripheral catheter, when the duration of IV therapy will likely exceed six days [83-85].
                                                                        Category IB

   Comment:
   Stipulation should be made for limiting the use of midline catheters to iso-osmolar and non-irritating or extravasating drugs to prevent thrombophlebitis/thrombosis.

   85. Ryder MA. Peripheral access options. Surg Oncol Clin N Am 1995;4:395-427

   Ryder M. Device selection: a critical strategy in the reduction of catheter-related complications. Nutrition: The International Journal of Applied and Basic Nutritional Sciences, 1996;12(2):143-145.

2. **Hand hygiene and aseptic technique**
   page 17; line 378
   2. Maintain aseptic technique for the insertion and care of intravascular catheters [25, 132-134].   Category IA

   Comment:
   Recommended aseptic technique during catheter care needs to be delineated. There is confusion as to best practice for aseptic technique during catheter maintenance procedures such as dressing changes, tubing changes, access site and hub disinfection, needleless connector changes, etc.

3. **Skin preparation**
   page 19; line 426
   2. Prepare clean skin site with a 2% chlorhexidine-based preparation before central venous catheter insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives

[140, 141].   Category IA

Comment:
What is the proper method to "clean" the skin? This is a step that is rarely included in protocols and unfortunately more rarely practiced. Line 326 states "The density of skin flora at the catheter insertion site is a major risk factor for CRBSI". The normal density of skin flora on the neck and chest is 10^5-10^6, a number difficult to eradicate or remove with an single "application" of antiseptic. Mechanical friction is an underlying principle of skin antisepsis. Suggest adding a chlorhexidine wash (cloth) as the cleansing step as recommended in Line 1479: Use a 2% chlorhexidine wash daily to reduce CRBSI [162].

Ryder M. Evidence based practice in the management of vascular access devices for home parenteral nutrition therapy. JPEN.2006;30:S82-S93.

4. catheter site dressing regimens
page 20; line 459
1. Use either sterile gauze or sterile, transparent, semi-permeable dressing to cover the catheter site [146-149].   Category IA

page 21; line 472
6. Replace dressings used on short-term CVC sites every 2 days for gauze dressings and at least every 7 days for transparent dressings, except in those pediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing.
                                                                        Category 1B

Comment:
Presuming the recommendation for the use of a 2% chlorhexidine skin preparation has been followed, maximum protection of the one-time application of the 2% chlorhexidine is 48 hours. Complete repopulation of skin flora will occur after loss of antiseptic activity. A 7-day dressing change leaves the insertion site and skin tract unprotected by an antimicrobial for up to 5 days and allows for complete regrowth of normal skin flora.

page 21; line 483
11. Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age, if the CRBSI rate is higher than the institutional goal, despite adherence to basic CRBSI prevention measures, including education and training, use of chlorhexidine for skin antisepsis, and MSB [22, 156-158].   Category 1B

Comments:
Five randomized controlled trials and one meta analysis have been published investigating the chlorexidine impregnated disc. Two RCTs[1,2] and the meta analysis[3] found significant reduction in catheter colonization, two RCTs[4,5] reported significant reduction in CRBSI, and one RCT[6] with significant reduction in exit site and tunneled infection. Classification criteria for a Category IA in this Guideline as stated on Page 3: line 71 Category IA. "Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies". Very few Category IA recommendations in this document have the same support of such strong evidence. Reconsideration of the Category IB to a Category IA for this recommendation should be made. The 7-day dressing change

recommendation for transparent dressings (with the CHG foam disc underneath) would then be validated. The disc should be placed at the time of insertion to allow for continuous protection for the 7 days and under gauze for protection in the presence of drainage. Either transparent dressing nor gauze have any antimicrobial protection especially in the presence of drainage.

1. Levy I, Katz J, Solter E, et al. Chlorhexidine-impregnated dressing for prevention of colonization of central venous catheters in infants and children: a randomized controlled study. Pediatr Infect Dis J 2005;24:676-91.

2. Garland JS, Alex CP, Mueller CD, et al. A randomized trial comparing povidone-iodine to a chlorhexidine gluconate-impregnated dressing for prevention of central venous catheter infections in neonates. Pediatrics 2001;107:1431-6.

3. Ho KM, Litton E. Use of chlorhexidine-impregnated dressing to prevent vascular and epidural catheter colonization and infection: a meta-analysis. J Antimicrob Chemother 2006;58:281-7

4. Timsit JF, Schwebel C, Bouadma L, et al. Chlorhexidine-impregnated sponges and less frequent dressing changes for prevention of catheter-related infections in critically ill adults: a randomized controlled trial. JAMA 2009;301:1231-41

5. Ruschulte H, Franke M, Gastmeier P, et al. Prevention of central venous catheter-related infections with chlorhexidine gluconate impregnated wound dressings: a randomized controlled trial. Ann Hematol 2009;88:267-72

6. Chambers ST, Sanders J, Patton WN, et al. Reduction of exit-site infections of tunneled intravascular catheters among neutropenic patients by sustained-release chlorhexidine dressing: results from a prospective randomised controlled trial. J Hosp Infect. 2005;61:53-61.

Ryder M. Evidence based practice in the management of vascular access devices for home parenteral nutrition therapy. JPEN.2006;30:S82-S93.

5. Replacement of Administration Sets
Page 46; line 1044.
1. In patients not receiving blood, blood products or lipid emulsions, replace administration sets, including secondary sets and add-on devices, no more frequently than at 96-hour intervals, [313] but at least every 7 days [255, 314-316].   Category IA

Needleless Intravascular Catheter Systems
Page 47; line 1066
1. Change the needleless components at least as frequently as the administration set. There is no benefit to changing these more frequently than every 72 hours [87, 328-334].
                                                                                    Category II
2. Change caps no more frequently than every 72 hours for the purpose of reduced infection rates or according to manufacturers' recommendations[328, 330, 333, 334].   Category II

Comments: These recommendations are not consistent. IV administration sets must have needleless devices for injection ports. (Page 48;Line 1077: 5. Use a needleless system to access IV tubing. Category IC). If left for 96 hrs this would be beyond the 72

hour recommendation for change. The manufacturer of "split septum" devices recommends a 24 hour change frequency due to increased risk of infection.

Recommendation for change frequency for secondary administration sets is advisable along with recommendation for protection of the male luer of the set when disconnected from the primary set.

Page 48;line 1078
6. When needleless systems are used, the split septum valve is preferred over the mechanical valve due to increased risk of infection [336-339]. Category II

Comments:
1. Classification of needleless connectors currently on the market **cannot** be simplified to a "split septum" and "mechanical valve" categorization due to the variability in the technology. There are three critical design features of these devices critical to patient outcomes namely CRBSI and catheter occlusion. These include the access portal, the flow path configuration, and the fluid displacement capability. There are no randomized controlled trials that examine and compare all available devices. There is one well-powered in vitro experimental study demonstrating significant differences among the devices in the ability of these devices to transfer bacteria when present and disinfection is not performed[1]. The split septum devices had a significantly higher rate of bacterial transfer rate in this study compared to the split septum/cannula and split septum/mechanical valves in the in vitro trial. Thus it is not possible to make generalizations regarding only two categories of devices.

2. The cited studies do not support the recommendation.

Four studies are cited in support of the recommendation[2-5]. Notably, all four of the referenced studies are retrospective, non-controlled, non-randomized observational studies from single study sites. Five devices with different device designs are reported in these studies: (1) the Interlink, a split septum/external blunt cannula device (SS) with negative displacement, (2) the Smartsite Plus and CLC2000, a mechanical valves with positive displacement (3) the Smartsite, a split septum/mechanical valve with negative displacement and (4) the Clave, and split septum/internal blunt cannula with negative displacement.
Maragakis, et al. reports a significant increase in the risk of CRBSI in intensive care patients with short-term catheters from a baseline rate of 1.5 per 1000 catheter days using a split septum/internal cannula device (Clave) to 2.4 per 1000 catheter days after changing to a positive displacement mechanical valve (PDMV) (Smartsite Plus), IRR 1.6 [95% CI, 1.04-2.48] p= .03[2].
Rupp, et al. also documented a significant increase in CRBSI risk in intensive care   patients with short term catheters after changing to the PDMV Smartsite Plus (10.64 per 1000 catheter days) from the Interlink SS (3.87 per 1000 catheter days); p= .001. The CRBSI rate was reduced to a higher than baseline rate of 5.59 but was still a significant reduction, p= .02. Nine inpatient units where the same devices were used were also studied with somewhat different results. Baseline rate with Interlink use was 3.47 per 1000 catheter days and increased to 7.3 with the same PDMV, p= .02. However, switching back to the Interlink did not result in a significant reduction, p= .57. The overall risk reduction was 3.32 [95% CI, 2.88-3.83] p= <.001. There was a significant risk for CRBSI in these two studies when changing from a split septum/internal cannula or a split septum/blunt cannula to the same PDMV[3]

In a different patient population of long-term acute care patients with peripherally inserted central catheters, Salgado, et al. reported a CRBSI rate of 1.79 per 1000 catheter days with Interlink SS to a rate of 5.95 after changing to the Smartsite, a split septum/mechanical valve needleless connector. The increased infection risk was significant with this change; RR 3.32 [95% CI, 2.88-3.83], p= < .001[4].

In the fourth referenced study, Field, et al. report a temporal change in CRBSI rates with initial use of the Interlink changing to the Clave and a PDMV device the CLC 2000, although it is unclear on this point as it specifically pictorially references and depicts the use of only two devices, the Interlink and the CLC2000. The report is further confusing in that the RR for the Interlink is a combined rate of the pre and post SS periods of use (2.6 per 1000 catheter days) compared to the supposed combined use of the Clave and a PDMV device the CLC 2000 (5.8 per 1000 catheter days); IRR 2.2, p= .031. These results are further called into question since some SSs were retained after the change to the PDMV device; no CABSI were recorded during the first week after the change to the PDMV, and three CABSI were recorded during the first week after the change back to the split septum device. This cluster of infections occurred within an approximate one-month period of time after several months of PDMV use wit equivalent rate of infection compared to the BCSS. The ambiguity of this report makes it difficult to include the results with any measure reliability or validity.

1. Ryder M, Fisher S, Hamilton G, et al. Bacterial transfer through needlefree connectors: comparison of nine different devices. The 17th Annual Scientific Meeting of the Society for Healthcare Epidemiology of America; April 2007.
2. Maragakis LL, Bradley KL, Song X, et al. Increased catheter-related bloodstream infection rates after the introduction of a New Mechanical Valve Intravenous Access Port. ICHE. 2006;27(1):67-70.
3. Rupp ME, Sholtz LA, Jourdan DR, et al. Outbreak of bloodstream infection temporally associated with the use of an intravascular needleless valve. CID. 2007;44:1408-14.
4. Salgado CD, Chinnes L, Paczesny TH, et al. Increased rate of catheter-related bloodstream infection associated with use of a needleless mechanical valve device at a long-term acute care hospital. ICHE. 2007;28(6):684-688.
5. Field K, McFarlane C, Cheng AC, Hughes AJ, et al. Incidence of catheter-related bloodstream infection among patients with a needleless, mechanical valve-based intravenous connector in an Australian hematology-oncology unit. ICHE. 2007;28(5):610-613.
6. Jarvis WR. Murphy C, Hall KK, et al. Health care-associated bloodstream infections associated with negative- or positive-pressure or displacement mechanical valve needleless connectors. CID. 2009;49:e-pub ahead.

3. The split septum may be less preferred than other luer-activated devices.

   a. The CRBSI rates reported for the split septum device in these studies were highly variable ranging 2.29 to 5.59 per 1000 catheter days and even higher in a recent paper at 8.17 per 1000 catheter days[5]. These rates are far above the desired target of zero CRBSI. The lowest rate of CRBSI reported in the cited studies was with the use of a split septum/internal cannula device at 1.5 per 1000 catheter days[2] a device not recommended under this suggestion.

   b. The split septum devices are negative placement devices, which are well known to increase catheter occlusion rates. This was the sole reason for the next generation, advanced technology creating neutral and positive displacement devices. Dramatic increase in catheter occlusion may be experienced.

c. The split septum/blunt cannula device can be accessed with a needle increasing potential risk for needlestick injury.

d. The split septum manufacturer's instructions for use recommend changing the device every 24 hours. This increases unnecessary hub manipulation and cost.

4. This recommendation will likely add to the confusion over the ongoing controversies regarding needleless connector use and selection. Practice changes may be made with disregard to the category of "suggested" information rather than sound scientific evidence required for a Category IA or B.

a. Many clinicians do not acknowledge, understand and most often ignore the categorization scheme used for labeling the strength of the recommendation. Too often unwarranted and significant practice changes are made in spite of the lack of evidence. This could lead to significant changes in undesirable outcomes.

b. This recommendation nor the cited studies do not take into account two other significant well documented factors that determine outcomes related to needleless devices; that is access device and catheter hub disinfection, and the frequency of change of the devices. It may be more beneficial for the Guidelines to focus more on "bundles" for prevention(no bundles are identified for the prevention of intraluminal infection) as described in the Performance Improvement section rather than isolating specific factors or devices as isolated causes or measures of intralumnial infection risk

c. This recommendation should at least be consistent with the SHEA/IDSA compendium strategies.

Page 48; line 1083

Stopcock contamination is common, occurring in 45% and 50% in the majority of series. Whether such contamination is a substantial entry point of CRBSI has been difficult to prove.

Comment:
Stopcocks are still widely used on vascular access devices particularly in critical care and anesthesia and are at high infection risk. However, infection prevention practices regarding these devices have gone virtually ignored in practice recommendation guidelines. Significant findings regarding the potential outcomes and consequences of stopcock contamination has been studied by Loftus[1]. Consideration should be given to recommendation for the use of needleless connectors on stopcocks or stopcock hub disinfection before accessing.

1. Loftus RW, Koff MD, Burchman CC, et al. Transmission of pathogenic bacterial organisms in the anesthesia work area. Anesthesiology. 2008;109:399-407.

With kind regard,

Marcia Ryder